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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,093	02/26/2002	Jeffrey J. Shea	10557/266546	5422

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,093

Applicant(s)

SHEA ET AL.

Examiner

Anu Ramana

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 13-18 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 13-18 and 25-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10, 13-18 and 25-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dye et al. (US 6,120,546) in view of Farris et al. (US 6,152,927) and Khalili (US 6,228,121).

Dye et al. disclose an implantable prosthesis 10 with screw holes 36 extending from a first surface 16 to a second surface 14 wherein a section of the hole at the second surface has a smaller diameter than a section of the hole at the first surface (Fig. 3, col. 1, lines 9-13 and col. 6, lines 58-65).

Dye et al. also disclose that portion 40 of the screw hole can be conical to receive a screw or "insertion member" with a spherically or "nonfrustoconical" undersurface for congruent or intimate contact inherently providing a "substantially fluid tight seal" (col. 7, lines 13-31).

Dye et al. do not disclose a screw hole having a proximal taper section at the first surface.

Farris et al. teach screw holes 34 in an implantable member wherein the proximal section of screw hole 34 has a flared or "frustoconical tapered" recess 79 to facilitate insertion of a screw (Figs. 7, 9 and 13 and col. 9, lines 47-49).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a proximal flare or "frustoconical taper" to the screw-receiving holes 36 of Dye et al., as taught by Farris et al., to facilitate insertion of screws.

Khalili teaches a type of insertion member or screw (108 and 110) having a rounded or spherical or "nonfrustoconical" contact surface that mates with a screw hole

wall 114 at a range of angles to provide access to desired regions of bone (col. 3, lines 28-33 and lines 61-67 and col. 4, lines 1-31).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a screw with head having a spherical undersurface, such as the type taught by Khalili, in a screw hole of the combination of Dye et al. and Farris et al., to allow for positioning of the screw at a range of angles to provide access to desired regions of bone.

Regarding claims 8, 17 and 26, Dye et al. disclose that their shell can be used in a well-known total hip joint prosthesis that includes an acetabular shell, an associated bearing liner and a femoral stem and an associated spherical head (col. 5, lines 60-67 and col. 6, lines 1-14).

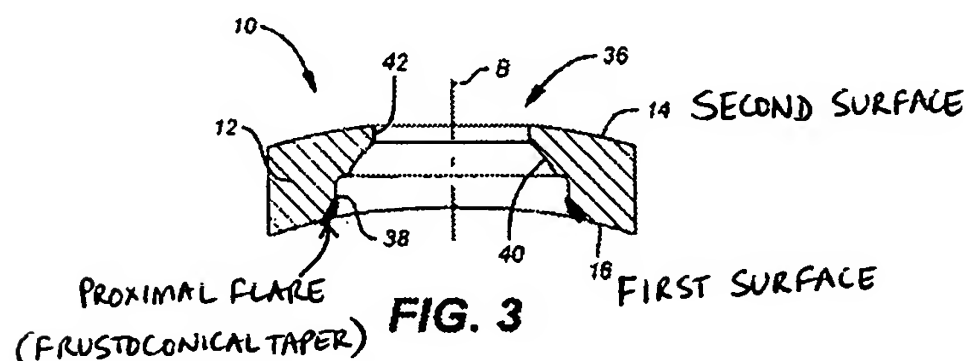
The method steps of claims 27-38 are performed during assembly and normal use of an implantable prosthesis of the combination of Dye et al., Farris et al. and Khalili, for total hip arthroplasty.

Response to Arguments

Applicants' arguments under "REMARKS" submitted in the response filed on October 14, 2004 with respect to the rejections of claims 1-8, 10, 13-18 and 25-38 under 35 USC 103(a) in the Office Action mailed on July 13, 2004 are not persuasive for the following reasons.

In response to applicant's argument on Page 13 under "REMARKS," that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Farris et al. clearly teaches flaring the proximal section of any screw hole to facilitate placement of a screw in the hole (Figs. 7, 9 and 13 and col. 9, lines 47-49). Thus, it would have been obvious to have provided a proximal flare to the

screw hole 36 of the Dye et al. shell to facilitate placement of a screw in the hole, as taught by Farris et al. See marked up Fig. 3 from Dye et al. below illustrating a screw hole with a proximal flare or “frustoconical taper,” in the device of the combination of Dye et al. and Farris et al.



Dye et al. clearly disclose contact between two differently shaped surfaces. See col. 7, lines 13-34) where it is stated that surface 40 of screw hole 36 can be conical and can receive screws with heads having spherical or conical undersurfaces (emphasis added).

Regarding Applicants' arguments that the combination Dye et al., Farris et al. and Khalili, does not disclose a fluid-tight relationship, the phrase "substantially fluid-tight" does not preclude the device of the combination of references because a screw placed in a screw hole in the device of the combination of the references blocks the screw hole and prevents fluid flow or migration of debris by congruent contact or "taper lock" between the screw head undersurfaces and the walls of the screw hole thus constituting a "substantially fluid-tight seal." Turning to Applicants' specification to determine what constitutes a "substantially fluid-tight seal," at page 23, line 21 and page 24, lines 1-2, Applicants' disclose that a head of an insertion member can be received and locked in a screw hole to provide "at least a partial seal." Applicants' also disclose on page 28, lines 20-23 that contact between the head portion 132 of insertion member 130 against wall 62 of opening 60 of acetabular cup 50 of Applicants' invention "lessens, and optimally curbs, migration of wear debris." Thus, the combination of Dye et al., Farris et al. and Khalili would form "at least a partial seal" and would lessen migration of wear debris and thus would be "substantially fluid tight."

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

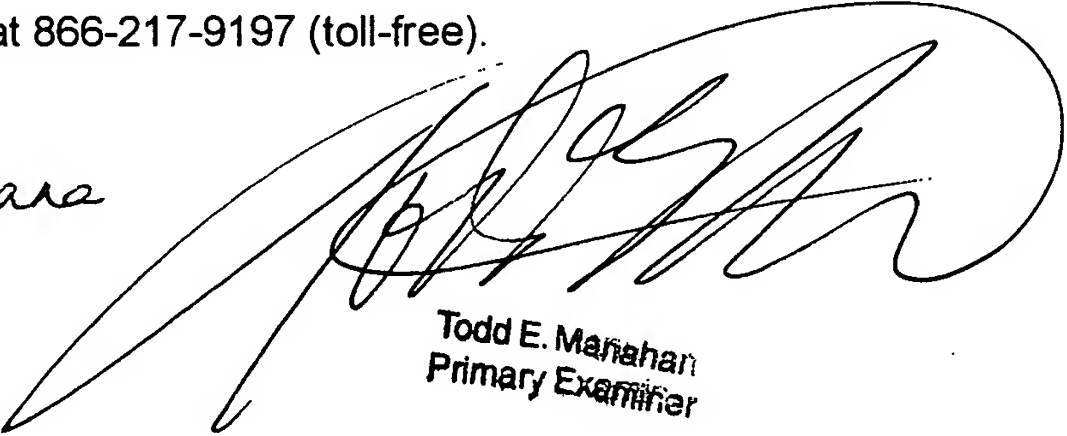
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anu Ramana*
December 22, 2004


Todd E. Manahan
Primary Examiner